

REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. No claim is allowed. Claims 2-5 and 7-12 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 2 and 7 have been objected to because they depend from non-elected claims. Appropriate correction is being made, thereby obviating this objection.

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to claim 4.

Claims 2, 4-5, 7, and 9-10 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while enabling for DNA with SEQ ID NO:2 or 6 encoding a polypeptide with SEQ ID NO:1 or 5 respectively, having hyperthermostable protease activity, does not reasonably provide enablement for any or all DNA encoding any or all hyperthermostable proteases or any DNA that can hybridize to either SEQ ID NO:2 or 6 or any DNA encoding a functional equivalent. This rejection is obviated by the amendment to claims 2 and 7 to delete "functional equivalent thereof" without prejudice and by the amendments to claims 4 and 9 to recite specific stringent hybridization conditions.

Claims 2, 4-5, 7 and 9-10 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The rejection as it relates to claims 2, 5, 7 and 10 is obviated by the amendments to the claims. With regard to amended claims 4 and 9, applicants invite the examiner's attention to Example 9 on hybridization in the Revised Interim Written Description Guidelines Training Material, where it states:

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Applicants believe that the fact situation in the present application is similar to Example 9 discussed above, and accordingly, the presently claimed invention is adequately described.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 2, 4-5, 7, and 9-10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Klingeberg et al.,

Appl. Microbiol. Biotechnol. 34:715-719 (1991) and the common knowledge in the art of molecular biology to clone a purified protein. The examiner takes the position that, because a polynucleotide made using the teachings of Klingenberg et al. would encode a hyperthermostable protease, such a polynucleotide would be capable of hybridizing to SEQ ID NOs: 2 or 5. This rejection is respectfully traversed.

This rejection as it relates to claims 2, 5, 7 and 10 is obviated by the amendments to claims 2 and 7 to direct the hyperthermostable protease to a specific identified sequence. With regard to rejected claims 4, 9 and new claims 11-12, Klingenberg does not disclose purified hyperthermostable proteases but rather only discloses the presence of hyperthermostable protease activity in the supernatant of a culture of hyperthermostable eubacteria such as *Thermoscoccus celer* and characterization of some properties. This is evident from the disclosure in the Materials and Methods section under "Cell-free extract", where it is disclosed that the supernatant of the media was concentrated and dialyzed. The concentrated and dialyzed supernatant was then used in the experiments in Klingenberg. Accordingly, there is no disclosure of a purified hyperthermostable protease in Klingenburg. Furthermore, there is absolutely no indication that a DNA encoding a hyperthermostable protease in Klingenburg which is not even purified could hybridize to the presently claimed polynucleotide under the specific

stringent hybridization conditions recited in claims 4 and 9. Accordingly, Klingeberg cannot make obvious the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Applicants have added into the present specification a substitute paper copy Sequence Listing section according to 37 C.F.R. §1.821(c). Furthermore, attached hereto is a 3 1/2" disk containing the "Sequence Listing" in computer readable form in accordance with 37 C.F.R. §1.821(e).

Applicants have amended the specification to insert SEQ ID Nos, as supported in the present specification.

The following statement is provided to meet the requirements of 37 C.F.R. §1.825(a) and 1.825(b).

I hereby state, in accordance with 37 C.F.R. §1.825(a), that the amendments included in the substitute sheets of the sequence listing are believed to be supported in the application as filed and that the substitute sheets of the sequence listing are not believed to include new matter.

I hereby further state, in accordance with 37 C.F.R. §1.825(b), that the attached copy of the computer readable form is

the same as the attached substitute paper copy of the sequence listing.

Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a

natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

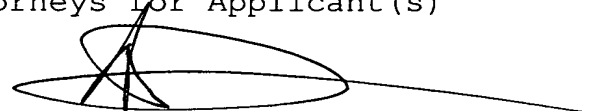
Applicants submit that the present application contains patentable subject matter and therefore urge the examiner to pass the case to issuance.

If the examiner has any questions or comments concerning the above described application, the examiner is urged to contact the undersigned at the phone number below.

Respectfully submitted,

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